DEPARTMENT OF HEALTH & HUMAN SERVICES
New York District

Food & Drug Administration
300 Pearl Street, Suite 100
Buffalo, NY 14202

m4093m

August 22, 2000

WARNING LETTER NYK 2000-93

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Maureen Seubert
Manager, Radiology
Chestnut Ridge Family Health Center
8280 Willett Parkway
Baldwinsville, New York 13027

RE: Facility ID Number 106484

Dear Ms. Seubert:

Your facility was inspected on July 11, 2000 by a representative of the New York State Department of Health, acting on behalf of the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following repeat Level 2 finding at your facility:

- ***The interpreting physician [redacted] did not meet the continuing education requirement of having completed a minimum of 15 CME credits in a 36-month period.***

The specific problem noted above appeared on your MQSA Facility Inspection Report which was issued to your facility at the close of the inspection. This problem is identified as repeat Level 2 because it identifies a failure to meet a significant MQSA requirement and indicates failure by your facility to implement permanent correction of a problem found during your previous inspection.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent violations of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction; charging your facility for the cost of on-site monitoring; assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with MQSA standards; suspension or revocation of your facility's FDA certificate; obtaining a court injunction against further mammography.

We received your letter dated July 28 responding to the inspectional findings. We acknowledge that Dr. Callahan is in the process of obtaining the 2 CMEs he requires. However, he has not currently met the above requirement, and therefore, he may not interpret mammograms independently from the date of the inspection until he receives the appropriate documentation of completed credits. This documentation needs to be forwarded to our office as soon as it is received. You may fax it to Edward W. Thomas at (716) 551-4499.

Finally, you should understand there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, Maryland 21045-6057 (1-800-838-7715), or through the Internet at http://www.fda.gov.

Sincerely,

Brenda J. Holman
District Director

cc: Priscilla F. Butler, M.S.
Director, Breast Imaging Accreditation Programs
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American College of Radiology
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cc: Gerald O'Connor
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